REMARKS OF THE

HONORABLE HENRY A. WAXMAN SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

TO THE

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I'm very pleased to be able to speak with you this afternoon and bring you up to date on some of the issues of concern to you, both as veterinarians and as consumers of healthcare services.

As chairman of the House Subcommittee on Health and the Environment, I can tell you this is a critical time to be concerned about health issues in America. Consider these facts:

* We've seen an explosion in the number of Americans with no form of health insurance. OF the 37 million people without coverage, nearly two-thirds of those are the

working poor and their families;

- * We underfund and undercut our health programs for the poor. Less than half of those people below the poverty line are eligible for Medicaid, and those who are covered too often have inadequate access to services from providers who are grossly underpaid;
- * And from New York City to Los Angeles, hospitals are so overburdened and underbudgetted that emergency rooms are closing, people are routinely turned away, and the situation only promises to get worse.

The fact is, a recent Harris poll showed that 89 percent of Americans thought the health care system in this country needed fundamental change.

We cut into our Medicare program, and pretend that it doesn't affect the quality or access to services that our senior citizens get. We cut into our Medicaid program and then pretend that babies aren't dying for lack of good prenatal care.

This session of Congress we are working on a number of pieces of legislation that would deal with these issues. With Senator Kennedy, I have introduced legislation that requires all employers to provide their workers with a minimum health benefits package. This bill would also expand the public program for those people not in the workforce, but in the meantime, we have a package of Medicaid expansions that would make prenatal and child health services available to more women and children, and would allow the elderly and individuals with mental retardation to receive care outside of nursing homes and institutions.

And finally, this may be the year when we make some real progress on some important environmental issues. While the issues are by no means resolved, we do seem to have all the players ready to agree on some form of Clean Air legislation. For the first time in years, the leadership in both the House and the Senate have made this environmental legislation one of their top

priorities. And while President Bush's Clean Air proposal is not as comprehensive as we'd like, the fact that he has introduced his own proposal is a dramatic shift from the days of a president who thought trees were the cause of air pollution.

As you can see, even just the big issues are enough to keep us busy until Christmas. But there are a host of other issues I'm concerned about, and among them are some which are of special interest to you.

ANIMAL WELFARE

I'd like to start by addressing some concerns about animal welfare. As veterinarians, you have dedicated your lives and professional careers to the promotion of animal welfare. In Washington you have provided critical support for maintaining the Inspection and Enforcement Programs under the Animal Welfare Act. Through the local animal shelter and animal hospital, veterinarians represent important and caring leaders in

the community. Through support of public education, and support of low cost neuter/spayed programs, the veterinary community provides essential services.

Recently we have witnessed a profound growth in public interest in animal welfare. It is manifested in both positive and negative forms.

The Membership in environmental groups like the Sierra Club has grown through appeals to those concerned about preserving wilderness and its wildlife. It is no accident that millions of Americans watched with concern and admiration the rescue efforts earlier this year of Alaskan Natives and a Russian ice breaker to free three whales trapped in ice. How many Americans were shocked and then angered by the destruction of wildlife resulting from the recent oil spills in Alaska and Antarctic?

Growing public concern about these kinds of incidents is a positive development, and hopefully it will bolster our efforts to

clean the air, water and conserve an environment we are only borrowing from our grandchildren.

There has also been a phenomenal growth in support for community animal shelters. Animal adoptions are up. We have more pet owners and more responsible pet owners. We know these are positive developments not just for animal control goals but also for human health. In 1987 the National Institutes of Health conducted a technology assessment workshop on the "Health Benefits of Pets." There is a developing body of medical evidence attesting to the therapeutic benefits of pet ownership. We are finding increasing use for animals in assisting the disabled, and lifting the spirits of the elderly. Some research shows that the relationship between a pet an its owner can actually reduce the incidence of illness by lowering blood pressure, heart rate and raising morale.

The growth in public interest in animal welfare is also demonstrated by the introduction of legislation in Congress.

During 1989 a variety of bills have been introduced. They are

referred to committees ranging from Agriculture to Ways and Means because the issues of animal welfare cut across committee jurisdictions. Some of the bills pending in Congress include studies regarding the treatment of animals sold through pet stores, prohibitions on the importation of Australian kangaroos and ivory, and providing protections to mice, rats and birds under the Animal Welfare Act.

The Subcommittee on Health and the Environment has jurisdiction over health research agencies like the NIH and regulatory agencies like the EPA and FDA. Accordingly, a significant number of animal welfare legislative proposals are directed our way. The legislation generally falls into two categories. The first, restrictions, improvements or revisions in the standards for conducting basic biomedical research involving animals. The second, seeking to prohibit or minimize the use of animals in product testing by banning or restricting the LD-50 and Draize tests. Although no action on these often contentious issues is scheduled, the Subcommittee is both keenly aware of the need for humane treatment of animals and vigilant to the threat

arbitrary or unscientific restrictions on animal use would pose to human health.

Let me be clear. Just as the use of animals in research is essential to expand knowledge and prevent disease in both animals and man, it is essential that the utmost care be taken to assure proper care and treatment of animals used in research. For this reason it was important for us that when Animal Care Committees were established in 1984 to assure compliance with NIH animal care guidelines, we insisted that a veterinarian participate as a member of that committee. Just as we must continue to strive to improve research techniques, we believe improvements can and should be made in the treatment of laboratory animals. In this regard we are hopeful that the final implementation of the 1985 Amendments to the Animal Welfare Act will enhance rather than disrupt the progress and conduct of research. Debate is healthy and improvements in the care and treatment of laboratory animals have resulted from the input you and other organizations have contributed to the policy making process.

So far we've discussed some of the positive developments of greater public support and concern over animal welfare. I would be remiss if I did not comment on another issue that is becoming of increasing concern to the research and health care community. That is the growth in membership and political activity of the so-called ANIMAL RIGHTS movement. The philosophy of this movement is characterized by an absolute opposition to the use of animals, particularly dogs and cats, in medical research. While its members represent only a small minority of public opinion, they are increasingly politically active and hold to an almost theological belief that the lives of humans and animals are morally equivalent. In their view of the world, a time may come when veterinarians would need to obtain informed consent from the patient rather than the owner.

In recent years members of a group calling itself the Animal Liberation Front have claimed credit for the deliberate vandalism of biomedical research facilities. Research equipment has been destroyed, laboratory documents stolen and animals released. We have received complaints from scientists about

anonymous threats against themselves and their families. As a result, some scientists have found it necessary to heed the threats, abandon the use of animals and in some cases end their research careers for more lucrative clinical practice.

These acts of intimidation and wanton violence can not be tolerated. Next week I will introduce legislation which will impose tough criminal penalties for the destruction of Federally funded research facilities or the intimidation of research personnel. By adding the intelligence and law enforcement resources of the Federal government, I am hopeful that those who are unwilling to express their views peacefully, will be apprehended and swiftly punished.

SAFE FOOD FROM FOOD-PRODUCING ANIMALS

Veterinarians and the public share common ground on more than animal welfare issues. You also share with the public a deep concern for the safety of food from food-producing animals. Consumers are far more aware today of the potential for health problems with food. From salmonella in chicken to pesticide residues in raw agricultural products, consumer sensitivity is higher than ever and consumer reaction time is short. The most recent example of the public's swift response to questions of potential adverse health effects is the virtual boycott of apples treated with the pesticide ALAR.

As veterinarians, I know you worry that the public can, and sometimes does, overreact to fear of chemical contamination. I believe the public's attitude toward animal drugs is the same as with pesticides and other added substances. They do not fully understand the importance of animal drugs for food-producing animals. Their only real concern is that any residues of animal drugs be safe for them to eat.

The important question for all of us is why the public is skeptical about the safety of our food. I believe a large part of the answer lies in the public's lack of confidence in government.

According to the Food Marketing Institute's recent survey of consumer attitude, 90 percent of the public say that product safety is important. In contrast, only 23 percent rely on the government to assure safety.

The federal government has not marshalled the scientific capacity nor learned the communication skills that are required in the 1980's. As you know so well, the Food and Drug Administration is severely underfunded and understaffed and has been for years. We spend as much on meat and poultry inspection as we do on the entire FDA.

The public deserves better. The food industry needs greater consumer confidence. I know veterinarians want to play a critical role in providing the public with the safest food supply we are capable of producing. It is Congress' job to give you the tools to do just that.

RESIDUE DETECTION METHODS

One tool I know you want and need is better residue detection methodologies to use in screening food-producing animals.

Veterinarians and producers alike want residue detection tests that are quick, reliable and, most importantly, validated by government. Certainly it is in consumer's interest for you and producers to screen food-producing animals at the farm for residues of unsafe chemicals. Greater involvement on the farm would be a major asset to the USDA's efforts to monitor meat and poultry at processing plants.

Currently, the methodologies available to you in the field cover too few drugs, are not sophisticated enough and are not validated by government. By leaving you in this position, we are missing an important opportunity to improve the safety of our food, as well as the public's perception of the safety of our food.

The government can move us forward by requiring the validation of these detection methods. Our goal of better residue

detection methods will require the coordination of government, the animal drug industry and veterinarians.

EXTRA-LABEL USE OF ANIMAL DRUGS

Another difficult problem for veterinarians is the lack of approved drugs you can use to treat animals. To be effective, you must often use approved drugs at doses, or in animals, which are not provided for in the drug's label.

While veterinarians firmly believe that these unapproved uses are clinically sound, drug companies have not sought their approval. The companies claim it costs too much. They say FDA testing requirements are unnecessarily strict. They fear FDA will impose new tests on the old, approved use if they go back to the agency for approval of a second use.

In short, your professional skills are hampered by an animal drug development and approval system that is unresponsive and understaffed. It does not serve you well. It

does not serve the public well.

The public's concern with extra-label use of animal drugs is a concern over food safety. As you know, the Food, Drug and Cosmetic Act requires that each use be tested for efficacy in the food-producing animal and for safety to consumers.

While the failure of our approval system might be understandable to you and me, the public is not so tolerant.

Their test of government's success is whether their food is free of unsafe animal drug residues. Unfortunately, we can not say with certainty that it is.

To resolve these outstanding questions and to regain the public's confidence, we must find solutions.

How can we get companies to seek approval of extra-label uses? Do we need incentives or requirements or both?

How can we get FDA the additional resources it so

desperately needs? How can we get veterinarians a broader range of approved drugs?

We need your ideas and your support if these tough problems are to be solved.

1988 GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT

In 1988 the Congress tried to answer the question of incentives for animal drug companies. In passing the Generic Animal Drug and Patent Term Restoration Act, we provided for up to five years of patent extension and up to 14 years of effective patent life for all approved uses of food-producing animal drugs.

In creating such a long exclusive market, we hoped companies would seek the approval of additional food uses so that they could lawfully promote those uses.

The other half of that important legislation was the creation of an expedited approval system for generic copies of off-patent brand name drugs. Our goal was to generate price competition for animal drugs.

The Generic Animal Drug bill was an important beginning.

But much more must be done before we will have adequately

addressed your needs and the public's concerns.

Conclusion

The issues before us are many. The experience and expertise you can provide is essential if Congress is to make informed decisions. I look forward to working with you.